

**REMARKS****Status of the Claims**

Claims 1-6, 9-13, 20 and 23-28 are pending in the present application, with claims 1 and 20 being independent claims. Claims 11 and 26 have been canceled. Claims 1, 12, 13, 20 and 27 have been amended. Applicants' acknowledge that when claims the elected species are found allowable, claims withdrawn to a non-elected species that require all the limitations of the allowable claims will be considered for rejoinder. In the event of the rejoinder, the restriction requirement will be withdrawn and the rejoined claims will be fully examined for patentability in accordance with 37 CFR 1.104.

In light of the amendments and remarks herein, Applicants' respectfully request reconsideration and allowance of the pending claims.

**Amendments to the Claims**

Applicants present the following amendments for the sole purpose of expediting prosecution of the pending claims. It is understood that such amendments are made without prejudice, and do not amount to Applicants' acceptance of the Office Action's rejections. Applicants reserve the right to prosecute any of the former forms of the claims in a continuing application.

Claim 1 has been amended to include "at least one minced tissue fragment containing a plurality of the viable cells; and". Support for the amendment can be found throughout the published specification, specifically in paragraphs [0009], [0040]-[0043] and [0044]-[0045] as well as Examples 1 and 3.

Claim 11 has been canceled.

Claims 12 and 13 have been amended to change dependency from claim 11 to claim 1.

Claim 20 has been amended to include: comprising: *(i)* an isolated biological tissue slice harvested from healthy tissue, having a geometry suitable for implantation at an injury or defect site, and *(ii)* *at least one minced tissue fragment, the tissue slice and minced tissue fragment*

*capable of acting as at least one source of viable cells ...allowing the viable cells to migrate...* Support for the amendments can be found throughout the published specification, specifically in paragraphs [0009], [0012], [0040]-[0043] and [0044]-[0045] as well as Example 1.

Claim 26 has been canceled.

Claim 27 has been amended to change dependency from claim 26 to claim 20.

No new subject matter has been added by these amendments.

### **Novelty**

Claims 1-6, 9, 11, 12, 20 and 23-28 currently stand rejected under 35 U.S.C. §102(b) as being anticipated by Badylak et al. (US Patent No. 6,485,723). The claims are directed to a biocompatible tissue implant comprising an isolated biological tissue slice and at least one *minced tissue fragment*. The current invention is novel because Badylak et al. do not disclose or suggest the use of a *minced tissue fragment*.

### ***Independent Claim 1***

Amended claim 1, recites a biocompatible tissue implant for repairing a tissue injury or defect. The claimed implant comprises an isolated biological tissue slice that acts as a cell source of viable cells, at least one *minced tissue fragment* and a retaining element that secures the implant to the implant site. In addition, the viable cells that migrate out of the biological tissue slice are also contained in the minced tissue fragment.

In the claimed invention, the advantage of adding a minced tissue fragment is exemplified in Example 3 when used in combination with cartilage plugs. The example shows better integration was observed when minced cartilage tissue was placed in close association with the cartilage plug. Specifically, histological examination found that cells from both minced tissue and the cartilage plugs were migrating out of the tissues into surrounding spaces and were responsible for bonding the entity together.

In contrast, Badylak et al. fail to disclose a *biological tissue slice* and *at least one minced tissue fragment*.

Badylak et al. disclose an artificial intestinal graft derived from delaminated submucosa matrix seeded with a cell population. No where do Badylak et al. mention the use of or suggestion of a biological tissue slice. As well, Badylak et al. provide no hint of using at least one minced tissue fragment any where in the reference.

Therefore, Badylak et al. do not anticipate claim 1 since they do not teach or suggest each and every element of claim 1. Since claims 2-6, 9, 12 and 28 depend directly or indirectly from amended claim 1, they are not anticipated for at least the same reasons as amended claim 1. In addition, the rejection to claim 11 is rendered moot by its cancellation.

#### *Independent Claim 20*

Amended claim 20 recites a method for repairing tissue injury or defect. The claimed method comprises using an isolated biological tissue slice harvested from healthy tissue with suitable geometry that is capable of acting as a cell source of viable cells and *at least one minced tissue fragment* as a biocompatible implant for tissue repair. The implant is delivered to a tissue site in need of repair and secured at the site of repair. Upon implantation, viable cells can migrate out of the tissue slice to proliferate and integrate with the tissue at the repair site.

As mentioned above for overcoming the rejection of amended claim 1, Badylak et al.'s artificial intestinal graft fails to utilize an *isolated biological tissue slice* and a *minced tissue fragment*.

Since Badylak et al. do not teach or suggest each and every element of the claimed method, amended claim 20 is not anticipated by Badylak et al. Furthermore claims 23-25 and 27 depend directly or indirectly on amended claim 20. Thus, the dependent claims are patentable for at least all the reasons mentioned above for amended claim 20. Also the cancellation of claim 26 renders its rejection moot.

Furthermore, in light of the arguments and remarks above, Applicants' respectfully request reconsideration and withdrawal of the 102 rejections.

**Obviousness**

Claim 13 currently stands rejected under 35 U.S.C. §103(a) as being unpatentable over Badylak et al. (US Pat. No. 6,485,723). Applicants respectfully disagree with the Examiner. As mentioned above for overcoming the 102 rejections of amended claim 1, Badylak et al. fail to disclose a biocompatible tissue implant comprising an *isolated biological tissue slice* and a *minced tissue fragment*.

Therefore, claim 1 is not obvious in light of Badylak et al.. Since claim 13 depends indirectly on amended claim 1 and incorporates the recitation of the patentable base claim, claim 13 is also patentable over the cited reference. Applicants therefore respectfully request the Examiner to reconsider and withdraw the 103 rejection to claim 13.

**CONCLUSION**

In view of the remarks above, Applicants submit that claims 1-6, 9-10, 12-13, 20, 23-25 and 27-28 are in condition for allowance, and allowance thereof is respectfully requested. Applicants encourage the Examiner to telephone the undersigned in the event that such communication might expedite prosecution of this matter.

A Petition for an Extension of Time is required to be submitted at this time, Applicants hereby petition under 37 CFR 1.136(a) for an extension of time for as many months as are required to ensure that the above-identified application does not become abandoned.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be filed or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Deposit Account No. 141449, under Order No. 22956-235.

Dated: July 28, 2008

Respectfully submitted,

By:



Charlton Shen  
Registration No. 54,442  
NUTTER MCCLENNEN & FISH LLP  
World Trade Center West  
155 Seaport Boulevard  
Boston, Massachusetts 02210-2604  
(617)-439-2437  
(617)-310-9437  
Attorney for Applicant

1747397.1